

(a) a nucleotide sequence comprising the following nucleotides from gi 1297184:  
nucleotides 11137-10900 followed by nucleotides 10506-10184 followed by 10090-9717; and

(b) a complement of the nucleotide sequence of (a);  
under conditions that permit formation of a nucleic acid duplex at a temperature from about 40-48°C below the melting temperature of the nucleic acid duplex.

### REMARKS

The title has been amended to more clearly describe the invention. In addition, claim 51 has been added. Support for claim 51 can be found in the gi 1297184 section of Table 1. Applicants have enclosed the relevant pages and have highlighted the pertinent section for the Examiner's convenience. No new matter has been added.

#### Rejections under 35 USC § 101

The Examiner has rejected claims 1-24 as lacking either specific and/or substantial utility or a well-established utility. The Examiner contends that neither the Specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds. Applicants respectfully traverse.

Table 1 provides the gi number (in this case, gi 1297184) which contains the claimed gene. This gi number is fully associated in Genbank with specific information about the gene(s) contained within it. The Genbank information provides functional information as well as citations to references. One skilled in the art understands the disclosure represented by the Genbank gi number. In this case, gene 0 of gi 1297184 has a well-established function. Thus, in view of the above, Applicants respectfully request reconsideration and removal of the rejection.

#### Rejections under 35 USC § 112, first paragraph

The Examiner has rejected claims 1-24 for lack of enablement. The Examiner contends that since no well-established utility exists, that one skilled in the art would not know how to use the claimed invention. Applicants respectfully traverse.

Applicants have shown that a well-established utility exists for the claimed sequence(s). One skilled in the art would know how to use these sequences based on their well-established utility(ies). In addition, the Specification provides guidance for the use of the claimed sequence(s) in several other contexts, such as for probes, markers, etc. Thus, Applicants respectfully request reconsideration and removal of the rejection.

The Examiner has also rejected claims 1-24 for lack of written description. The Examiner contends that the Specification does not disclose “how the provided sequences are in relation to the elected gene 0 <1297184>.” The Examiner also contends that the fragments of sequences of the provided sequences, corresponding sequences from other species, mutated fragment sequences, allelic variants and splice variants that the claims also encompass have no support within the Specification. Applicants respectfully traverse.

Table 1 discloses the relationship between the claimed sequence(s) and the sequence represented by the gi number. Table 1 lists the sequences of the exons that comprise the claimed sequence. Applicants have indicated in claims 1-5 and new claim 51 the exact exon sequence(s) claimed and their order. For example, Table 1 indicates whether the nucleotide sequence that encodes an amino acid is comprised of a single exon (denoted in the Table as “sngl”) or multiple exons. In the case of multiple exons, Table 1 provides an order by denoting the initial exon (Init), internal exon(s) (Intr) and terminal exon (Term). In addition, the Table provides the nucleotide numbers of the exon(s) (e.g. 5992-6048) as well as the direction of the order of the sequences (e.g. “+” indicating that the exons are joined in a 5’ to 3’ direction). The Specification also provides description and guidance as to identifying and isolating the various fragments of sequences, corresponding sequences from other species, allelic variants and splice variants. In addition the Specification provides description and guidance as to producing and/or obtaining mutated fragment sequences. Thus, Applicants urge that they have met the written description requirement and therefore request reconsideration and removal of the rejection.

#### Rejections under 35 USC § 112, 2<sup>nd</sup> paragraph

The Examiner has rejected claims 1-5 for lack of clarity as to the definition of gene 0 <1297184>. In addition, she contends that the meaning of the limitation “the complement” is unclear as is the phrase “a temperature from about 40°C and 48°C below.” Applicants respectfully traverse.

Applicants have amended the claims to specifically indicate the nucleotides comprising the exons of the claimed sequence and their order, thus obviating the rejection based on the clarity of the definition of the gene. In addition, Applicants have amended the claims to read “40-48°C below,” thus obviating the rejection. Lastly, Applicants have used the term “complement” as defined in the art. That is “complementary base sequence a sequence in a polynucleotide chain in which all the bases are able to form base pairs with a sequence of bases in another polynucleotide chain.” Oxford Dictionary of Biochemistry and Molecular Biology, 1997, eds. Smith et al., New York. Since this term is standard in the art, Applicants contend that no further definition is required and that the rejection should therefore be removed.

#### Rejections under 35 USC § 102 and 103

The Examiner has rejected claims 1-9 as obvious over SEQ ID 1 and SEQ ID 2 of US Patent No. 5,992,554 (‘554). The Examiner bases her rejection on the contention that Applicants have not limited the % complementarity in the instant claims. Applicants respectfully traverse.

As Applicants note above, the complement of a nucleic acid sequence is defined as a “polynucleotide claim in which *all* the bases are able to form base pairs with a sequence of bases in another polynucleotide chain.” (emphasis added). Given this definition, the sequences of the ‘554 patent do not disclose or suggest the instant invention. Thus, Applicants respectfully request reconsideration and removal of the rejection.

#### Claim Objections

The Examiner objects to the reference of a Table within the claims. Applicants have amended the claims to remove this reference, thereby overcoming the objection.

#### Specification Objections

The Examiner objects to the Specification based on the presence of hyperlinks and/or other form or browser-executable code. Applicants note the Examiner’s objection and Applicants shall amend the Specification to remove these items after the claims have been allowed.

In view of the above remarks, all the claims remaining in the case, including newly added claims, are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

Attached hereto is a marked-up version of the changes made to the Application by this amendment.

If the Examiner has any questions concerning this response which can be resolved by telephone, the Examiner is requested to contact the undersigned at (714) 708-8555.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of \$445.00 should be charged to Deposit Account No. 50-1055.

If the Primary Deposit Account No. 50-1055 is deficient and non-payment will result in a loss of rights, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to Commissioner of Patents and Trademarks, Washington

U.S. 30231 on: February 25, 2002  
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

*James R. Paul*  
(Signature)

02-25-02  
(Date of Signature)

2750-0942P  
LRS/SWG

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By *Leonard R. Svensson*

Leonard R. Svensson  
Registration No. 30, 330  
P.O. Box 747  
Falls Church, VA 22040-0747  
(714) 708-8555

Attachments: Version with Markings to Show Changes Made



VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

1. (Amended) An isolated nucleic acid molecule comprising a nucleic acid having a nucleotide sequence which encodes an amino acid sequence exhibiting at least 40% sequence identity to an amino acid encoded by

- (a) a nucleotide sequence [described in Table 1] comprising the following nucleotides from gi 1297184: nucleotides 11137-10900 followed by nucleotides 10506-10184 followed by 10090-9717, or fragment thereof; or
- (b) a complement of [a] the nucleotide sequence [shown in Table 1] of (a) or a fragment thereof.

2. (Amended) An isolated nucleic acid molecule comprising a nucleic acid having a nucleotide sequence which exhibits at least 65% sequence identity to

- (a) a nucleotide sequence [shown in Table 1] comprising the following nucleotides gi 1297184: nucleotides 11137-10900 followed by nucleotides 10506-10184 followed by 10090-9717, or fragment thereof; or
- (b) a complement of [a] the nucleotide sequence [described in Table 1] of (a) or a fragment thereof.

3. (Amended) An isolated nucleic acid molecule comprising a nucleic acid having a nucleotide sequence which exhibits at least 65% sequence identity to a gene comprising

- (c) a nucleotide sequence [shown in Table 1] comprising the following nucleotides from gi 1297184: nucleotides 11137-10900 followed by nucleotides 10506-10184 followed by 10090-9717, or fragment thereof; or
- (d) a complement of [a] the nucleotide sequence [described in Table 1] of (a) or a fragment thereof.

5. (Amended) An isolated nucleic acid molecule comprising a nucleic acid capable of hybridizing to a nucleic acid having a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence [Table 1] comprising the following nucleotides from gi 1297184: nucleotides 11137-10900 followed by nucleotides 10506-10184 followed by 10090-9717; and

(b) a nucleotide sequence which is complementary to [a] the nucleotide sequence shown in [Table 1] (a);

under conditions that permit formation of a nucleic acid duplex at a temperature from about 40°C and ]-48°C below the melting temperature of the nucleic acid duplex.